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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,378	07/14/2003	Steven Walkley	2543-1-022PCT/CIP	5426

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,378	WALKLEY, STEVEN	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,28,29 and 36-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 22, 28, 29 and 36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Final Office Action is a reply to the Paper filed 10 December 2007 in response to the Non-final Office Action mailed 8 August 2007. Claims 21, 22, 28, 29, and 36-39 were considered in the 8 August Office Action. Claims 21, 22, 28, 29, and 36-39 were amended in the 10 December Paper. Claims 21, 22, 28, 29 and 36-39 are pending and under consideration.

Response to Amendment and Arguments

Support for Claim Amendments

It is noted that, in addition to the passages cited in Applicant's remarks, support for the method "consisting of" administering NB-DNJ can be found in Example 3, paragraphs 131-138 of the originally filed specification.

Claim Rejections - 35 USC § 112

Rejection of claims 22, 29 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite is **withdrawn** in view of the claim amendments.

Claim Rejections - 35 USC § 102

Rejection of claims 21, 22, 28, 29, 36 and 37-39 under 35 U.S.C. 102(e) as being anticipated by Meeker et al. U.S. Pub. No. 2002/0095135 is **withdrawn** in view of the amendment of the claims to require that method "consists of" administering NB-DNJ or NB-DGJ.

Rejection of claims 21, 28 and 36-38 rejected under 35 U.S.C. 102(b) as being anticipated by Dwek et al. WO 00/62779 (made of record in the IDS filed 15 January 2004) is **withdrawn** in view of the amendment of the claims to require that method "consists of" administering NB-DNJ or NB-DGJ. Dwek et al. does not explicitly teach a method consisting of administering NB-DNJ.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21, 28 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dwek et al. WO 00/62779 (made of record in the IDS filed 15 January 2004).

Dwek et al. contemplates treating patients having mucopolysaccharidosis disease by administering the imino sugar inhibitors of glucosylceramide synthase N-butyldeoxynojirimycin and N-butyldeoxygalactonojirimycin. (See especially, the abstract; page 4, lines 13 and 20-21; page 7, lines 11-19; and the paragraph bridging pages 10-11.) Dwek et al. does not explicitly teach that the method might consist of administering the glucosylceramide synthase. However, on page 6, Dwek et al. contemplates a product comprising an inhibitor of glycolipid synthesis and an agent a capable of increasing the rate of glycolipid degradation, wherein the components can be used separately in the treatment of a disorder which has at least one component based on

glycolipid storage. (Page 6, lines 16-17.) Dwek goes on to state, "[I]t is envisaged that NB-DNJ (or any other inhibitor of glycolipid synthesis) can be administered to a patient with a glycolipid storage disease in order to maintain low levels of glycolipids. If the dosage of NB-DNJ is incorrect for any reason, an agent for increasing the rate of glycolipid degradation can be administered to restore the low levels of glycolipids."

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to practice the method of treating patients having mucopolysaccharidosis disease by administering NB-DNJ or NB-DGJ as contemplated by Dwek et al., wherein the method consists of administering only said a NB-DNJ or NB-DGJ. Although Dwek et al. contemplates combination therapies, Dwek et al. also teaches that small molecule inhibitors such as NB-DNJ can be administered independent of other agents and that agents for increasing the rate of glycolipid degradation are administered only if the dosage of NB-DNJ is incorrect. Given these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made that, if the dosage of NB-DNJ is not incorrect, the method would consist of administering only NB-DNJ or any other inhibitor of glycolipid synthesis. Absent evidence to the contrary, one would have a reasonable expectation of success in practicing the method consisting of administering NB-DNJ or NB-DGJ because Dwek et al. demonstrates that substrate deprivation by NB-DNJ alone is capable of extending the life-span of a mouse model of glycolipid storage disease. (See especially Example 2 and Figure 1.) Therefore, one would reasonably expect that the administration of inhibitors of glucosylceramide synthase would result in the outcomes recited in the instant claims.

In view of the foregoing, the invention of independent claims 21, 28 and 36-38, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims are properly rejected under 35 USC §103(a) as obvious over Dwek et al.

Claims 22, 29, and 39 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Dwek et al. (*supra*), as applied to claims 21, 28 and 38 above, further in view of Danos et al. (1995) *Mol. Cell Biol. Hum. Dis.*5:530-567. This rejection is rewritten herein to account for then new limitation of the method to "consisting of" administering NB-DNJ or NB-DGJ

As described above, Dwek et al. teaches a method of treating mucopolysaccharidosis that renders obvious the method of the instant claims 21, 28 and 38 as a whole. Dwek et al. does not specifically identify the MPS conditions recited in claims 22, 29 and 39.

Table 17.1 of Danos et al. shows that the various conditions recited in claims 22, 29 and 39 were recognized in the art as forms of mucopolysaccharidoses at the time that Dwek et al. was published. It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat any of the art recognized forms of mucopolysaccharidosis, such as those taught by Danos et al., according to the teachings of Dwek et al. One would be motivated to treat any and all known forms of mucopolysaccharidosis disease as contemplated by Dwek et al., including those conditions taught by Danos et al., in order to obtain the expected benefit of therapy.

Absent evidence to the contrary, one would have a reasonable expectation of success in practicing the method consisting of administering NB-DNJ or NB-DGJ because Dwek et al.

demonstrates that substrate deprivation by NB-DNJ alone is capable of extending the life-span of a mouse model of glycolipid storage disease. (See especially Example 2 and Figure 1.) Therefore, one would reasonably expect that the administration of inhibitors of glucosylceramide synthase as contemplated by Dwek et al. would result in the outcomes recited in the instant claims.

In view of the foregoing, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Therefore, the claims are properly rejected under 35 USC § 103(a).

Response to Arguments

In response to the *prima facie* rejection of record, Applicant contends that the art fails to teach a method "consisting of" administering only an imino sugar inhibitor of glucosylceramide synthase. In particular, Applicant submits that Dwek et al. contemplates only combination therapy and that each aspect of the invention described by Dwek et al. requires combination therapy.

This argument has been fully considered but is not deemed persuasive. As described above, the fourth aspect of the method taught by Dwek et al., described on page 6, teaches that the inhibitor of glycolipid synthesis and the agent capable of increasing the rate of glycolipid degradation can be administered separately and that the agent for increasing degradation is administered only if the dosage of NB-DNJ (or any other inhibitor of glycolipid synthesis) is incorrect. In view of this teaching alone, it would have been obvious to the skilled artisan that, if the dosage of the inhibitor of glycolipid synthesis is not incorrect, the method will consist of

administering only the synthesis inhibitor. Therefore, a method consisting of administering only NB-DNJ or NB-DGJ would have been obvious to one of ordinary skill in the art in view of the teachings of Dwek et al. alone. The teachings of Danos et al. are relied upon only to demonstrate that the various conditions recited in the claims were known to one of ordinary skill in the art at the time of invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M Sullivan/
Primary Examiner, Art Unit 1636